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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,894	09/28/2001	Toru Takehisa	011307	1326
23850	7590	10/24/2003	EXAMINER	
ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP			MACHUGA, JOSEPH S	
1725 K STREET, NW			ART UNIT	PAPER NUMBER
SUITE 1000				3762
WASHINGTON, DC 20006			DATE MAILED: 10/24/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/964,894	TAKEHISA ET AL.
	Examiner	Art Unit
	Joseph S. Machuga	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 and 6</u> . | 6) <input type="checkbox"/> Other: _____ . |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anazawa et al (#5192320) in view of Kashiwabara et al (EP-1057492) and Motomura et al (EP-0769503.)

Anazawa et al disclose an artificial lung. The reference teaches (note column 6 lines 22-52) that the membrane of the device should be made of poly(4-methylpentene-1.) The O₂ and ethanol permeation rates disclosed in the reference are within the limits defined in the claims. Not disclosed by this document is the surface coating that is derived from heparin and a quaternary aliphatic alkyl ammonium salt.

Kashiwabara et al disclose a blood compatible composition for use as a coating material in medical devices such as a pump-oxygenator, artificial heart, etc. The essential material in the composition is an organic cationic compound and heparin or heparin derivative. The reference teaches (note paragraph 22) that in addition to an organic cationic compound having between 24-32 carbon atoms the compound can include an organic cationic compound having 4 alkyl groups and more than 32 carbon atoms. In Example 3, dimethyl didodecyl ammonium chloride and dimethyl ditetradecyl

ammonium chloride were mixed in the proportions claimed. Thereafter heparin was dissolved in the mixture. The resulting product was a coating material having anti-thrombogenic properties.

Motomura et al teach that dimethyl ditetradecyl ammonium salt and dimethyl dioctadecyl ammonium salt are cationic compound having similar properties and produce similar results when dissolved with heparin (note claim 3 and the example on page 5.)

Given these disclosures, it would have been obvious to one of ordinary skill in the art to add Kashiwabara et al's coating to the blood contacting side of the membrane in Anazawa et al's device for the purpose of impart anti-thrombogenic properties thereto. To use dimethyl dioctadecyl ammonium salt in place of dimethyl ditetradecyl ammonium salt in Kashiwabara et al's product and process (noted above) would also have been obvious to one of ordinary skill in the art given Motomura et al's teaching that they are known equivalents for this purpose and would result in predictable variations in the lifetime of the coating, capability of the coating, etc.

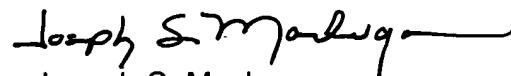
3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is **(703) 872-9306**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Joseph S. Machuga
Examiner
Art Unit 3762



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700